Exhibit D

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

STACY HOLK,

Plaintiff,

v.

CADBURY SCHWEPPES AMERICAS BEVERAGES, SNAPPLE BEVERAGE CORPORATION, SNAPPLE DISTRIBUTORS, INC., COTT QUALITY BEVERAGE, INC., ESSEX COTT DISTRIBUTORS, INC., and JOHN DOE (fictitious -- representing one or more persons or entities involved in the manufacture, sale and/or distribution of the products identified herein but whose identity is currently unknown),

Defendants.

Civil Action No. 3:07-cv-03018-MLC-JJH

EXHIBIT B

INDEX TO REGULATIONS

1. **21 C.F.R. §7.40**
2. **21 C.F.R. §10.25**
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5. **21 C.F.R. § 100.1**
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32. 21 C.F.R. § 101.83

33. 21 C.F.R. § 101.100

34. 21 C.F.R. §102.5

35. 21 C.F.R. §102.33

36. 21 C.F.R. §202.1

37. 56 FR 60421, 60,466

38. **58 FR 2302, 2407**

39. **58 FR 2897, 2921-2**

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21 C.F.R. § 7.40

C

Effective: [See Text Amendments]

Code of Federal Regulations Currentness
Title 21. Food and Drugs
Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)
Subchapter A. General
Part 7. Enforcement Policy (Refs & Annos)
Subpart C. Recalls (Including Product Corrections)--Guidance on Policy, Procedures, and Industry Responsibilities (Refs & Annos)

→§ 7.40 Recall policy.

(a) Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. This section and §§ 7.41 through 7.59 recognize the voluntary nature of recall by providing guidance so that responsible firms may effectively discharge their recall responsibilities. These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall.

(b) Recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Food and Drug Administration. A request by the Food and Drug Administration that a firm recall a product is reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled.

(c) Recall is generally more appropriate and affords better protection for consumers than seizure, when many lots of product have been widely distributed. Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a recall requested by the Food and Drug Administration, or where the agency has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing.

[65 FR 56476, Sept. 19, 2000]

SOURCE: 42 FR 15567, March 22, 1977; 43 FR 26218, June 16, 1978; 54 FR 39631, Sept. 27, 1989; 55 FR 9079, March 9, 1990; 62 FR 51512, Oct. 1, 1997; 65 FR 56476, Sept. 19, 2000, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321-393; 42 U.S.C. 241 , 262, 263b-263n, 264.

21 C. F. R. § 7.40, **21 CFR § 7.40**

Current through July 19, 2007; 72 FR 39581

END OF DOCUMENT

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21 C.F.R. § 10.25

C

Effective: [See Text Amendments]

Code of Federal Regulations Currentness
Title 21. Food and Drugs
Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)
Subchapter A. General
Part 10. Administrative Practices and Procedures (Refs & Annos)
Subpart B. General Administrative Procedures

➡§ 10.25 Initiation of administrative proceedings.

An administrative proceeding may be initiated in the following three ways:

(a) An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. A petition must be either: (1) In the form specified in other applicable FDA regulations, e.g., the form for a color additive petition in § 71.1, for a food additive petition in § 171.1, for a new drug application in § 314.50, for a new animal drug application in § 514.1, or (2) in the form for a citizen petition in § 10.30.

(b) The Commissioner may initiate a proceeding to issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action. FDA has primary jurisdiction to make the initial determination on issues within its statutory mandate, and will request a court to dismiss, or to hold in abeyance its determination of or refer to the agency for administrative determination, any issue which has not previously been determined by the agency or which, if it has previously been determined, the agency concluded should be reconsidered and subject to a new administrative determination. The Commissioner may utilize any of the procedures established in this part in reviewing and making a determination on any matter initiated under this paragraph.

(c) The Commissioner will institute a proceeding to determine whether to issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action whenever any court, on its own initiative, holds in abeyance or refers any matter to the agency for an administrative determination and the Commissioner concludes that an administrative determination is feasible within agency priorities and resources.

[54 FR 9034, March 3, 1989]

SOURCE: 44 FR 22323, April 13, 1979; 54 FR 6885, Feb. 15, 1989; 54 FR 39631, Sept. 27, 1989; 55 FR 9079, March 9, 1990; 58 FR 49190, Sept. 22, 1993; 62 FR 51512, Oct. 1, 1997; 63 FR 32735, June 16, 1998; 65 FR 25440, May 2, 2000, unless otherwise noted.

AUTHORITY: 5 U.S.C. 551-558, 701-706; 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

21 C. F. R. § 10.25, **21 CFR § 10.25**

Current through July 19, 2007; 72 FR 39581

END OF DOCUMENT

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21 C.F.R. § 10.30

C

Effective: [See Text Amendments]

Code of Federal Regulations Currentness
Title 21. Food and Drugs
Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)
Subchapter A. General
Part 10. Administrative Practices and Procedures (Refs & Annos)
Subpart B. General Administrative Procedures

➡§ 10.30 Citizen petition.

(a) This section applies to any petition submitted by a person (including a person who is not a citizen of the United States) except to the extent that other sections of this chapter apply different requirements to a particular matter.

(b) A petition (including any attachments) must be submitted in accordance with § 10.20 and in the following form:

(Date)_____

_____

Division of Dockets Management, Food and Drug Administration, Department of Health and Human Services, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Citizen Petition

The undersigned submits this petition under ___ (relevant statutory sections, if known) of the ___ (Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10) to request the Commissioner of Food and Drugs to ___ (issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action).

A. Action requested

((1) If the petition requests the Commissioner to issue, amend, or revoke a regulation, the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested.)

((2) If the petition requests the Commissioner to issue, amend, or revoke an order, a copy of the exact wording of the citation to the existing order (if any) and the exact wording requested for the proposed order.)

((3) If the petition requests the Commissioner to take or refrain from taking any other form of administrative action, the specific action or relief requested.)

B. Statement of grounds

(A full statement, in a well organized format, of the factual and legal grounds on which the petitioner relies, including all relevant information and views on which the petitioner relies, as well as representative information known to the petitioner which is unfavorable to the petitioner's position.)

C. Environmental impact

(A) Claim for categorical exclusion under §§ 25.30, 25.31, 25.32, 25.33, or § 25.34 of this chapter or an environmental assessment under § 25.40 of this chapter.)

D. Economic impact

(The following information is to be submitted only when requested by the Commissioner following review of the petition: A statement of the effect of requested action on: (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5)

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employment; and (6) energy supply or demand.)

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(Signature) _____
_____

(Name of petitioner)
_____
_____

(Mailing address)
_____
_____

(Telephone number)_____
_____

(c) A petition which appears to meet the requirements of paragraph (b) of this section and § 10.20 will be filed by the Division of Dockets Management, stamped with the date of filing, and assigned a docket number. The docket number identifies the file established by the Division of Dockets Management for all submissions relating to the petition, as provided in this part. Subsequent submissions relating to the matter must refer to the docket number and will be filed in the docket file. Related petitions may be filed together and given the same docket number. The Division of Dockets Management will promptly notify the petitioner in writing of the filing and docket number of a petition.

(d) An interested person may submit written comments to the Division of Dockets Management on a filed petition, which comments become part of the docket file. The comments are to specify the docket number of the petition and may support or oppose the petition in whole or in part. A request for alternative or different administrative action must be submitted as a separate petition.

(e)(1) The Commissioner shall, in accordance with paragraph (e)(2), rule upon each petition filed under paragraph (c) of this section, taking into consideration (i) available agency resources for the category of subject matter, (ii) the priority assigned to the petition considering both the category of subject matter involved and the overall work of the agency, and (iii) time requirements established by statute.

(2) Except as provided in paragraph (e)(4) of this section, the Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either:

(i) Approve the petition, in which case the Commissioner shall concurrently take appropriate action (e.g., publication of a Federal Register notice) implementing the approval;

(ii) Deny the petition; or

(iii) Provide a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information. The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished.

(3) The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants. The petitioner is to be notified in writing of the Commissioner's decision. The decision will be placed in the public docket file in the office of the Division of Dockets Management and may also be in the form of a notice published in the Federal Register.

(4) The Commissioner shall furnish a response to each petitioner within 90 days of receipt of a petition filed under section 505(j)(2)(C) of the act. The response will either approve or disapprove the petition. Agency action on a petition shall be governed by § 314.93 of this chapter.

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(f) If a petition filed under paragraph (c) of this section requests the Commissioner to issue, amend, or revoke a regulation, § 10.40 or § 10.50 also apply.

(g) A petitioner may supplement, amend, or withdraw a petition in writing without agency approval and without prejudice to resubmission at anytime until the Commissioner rules on the petition, unless the petition has been referred for a hearing under parts 12, 13, 14, or 15. After a ruling or referral, a petition may be supplemented, amended, or withdrawn only with the approval of the Commissioner. The Commissioner may approve withdrawal, with or without prejudice against resubmission of the petition.

(h) In reviewing a petition the Commissioner may use the following procedures:

(1) Conferences, meetings, discussions, and correspondence under § 10.65.

(2) A hearing under parts 12, 13, 14, 15, or 16.

(3) A Federal Register notice requesting information and views.

(4) A proposal to issue, amend, or revoke a regulation, in accordance with § 10.40 or § 12.20.

(5) Any other specific public procedure established in this chapter and expressly applicable to the matter.

(i) The record of the administrative proceeding consists of the following:

(1) The petition, including all information on which it relies, filed by the Division of Dockets Management.

(2) All comments received on the petition, including all information submitted as a part of the comments.

(3) If the petition resulted in a proposal to issue, amend, or revoke a regulation, all of the documents specified in § 10.40(g).

(4) The record, consisting of any transcripts, minutes of meetings, reports, Federal Register notices, and other documents resulting from the optional procedures specified in paragraph (h) of this section, except a transcript of a closed portion of a public advisory committee meeting.

(5) The Commissioner's decision on the petition, including all information identified or filed by the Commissioner with the Division of Dockets Management as part of the record supporting the decision.

(6) All documents filed with the Division of Dockets Management under § 10.65(h).

(7) If a petition for reconsideration or for a stay of action is filed under paragraph (j) of this section, the administrative record specified in § 10.33(k) or § 10.35(h).

(j) The administrative record specified in paragraph (i) of this section is the exclusive record for the Commission's decision. The record of the administrative proceeding closes on the date of the Commissioner's decision unless some other date is specified. Thereafter any interested person may submit a petition for reconsideration under § 10.33 or a petition for stay of action under § 10.35. A person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new petition to modify the decision in accordance with this section.

(k) This section does not apply to the referral of a matter to a United States attorney for the initiation of court enforcement action and related correspondence, or to requests, suggestions, and recommendations made informally in routine correspondence received by FDA. Routine correspondence does not constitute a petition within the meaning of this section unless it purports to meet the requirements of this section. Action on routine correspondence does not constitute final administrative action subject to judicial review under § 10.45.

(l) The Division of Dockets Management will maintain a chronological list of each petition filed under this section and § 10.85, but not of petitions

submitted elsewhere in the agency under § 10.25(a)(1), showing:

(1) The docket number;

(2) The date the petition was filed by the Division of Dockets Management;

(3) The name of the petitioner;

(4) The subject matter involved; and

(5) The disposition of the petition.

[44 FR 22323, April 13, 1979; 46 FR 8455, Jan. 27, 1981; 50 FR 16656, April 26, 1985; 54 FR 9034, March 3, 1989; 57 FR 17980, April 28, 1992; 59 FR 14364, March 28, 1994; 62 FR 40592 , July 29, 1997; 66 FR 6467, Jan. 22, 2001; 66 FR 12848, March 1, 2001]

SOURCE: 44 FR 22323, April 13, 1979; 54 FR 6885, Feb. 15, 1989; 54 FR 39631, Sept. 27, 1989; 55 FR 9079, March 9, 1990; 58 FR 49190, Sept. 22, 1993; 62 FR 51512, Oct. 1, 1997; 63 FR 32735 , June 16, 1998; 65 FR 25440, May 2, 2000, unless otherwise noted.

AUTHORITY: 5 U.S.C. 551-558, 701-706; 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

21 C. F. R. § 10.30, **21 CFR § 10.30**

Current through July 19, 2007; 72 FR 39581

END OF DOCUMENT

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21 C.F.R. § 10.85

C

Effective: [See Text Amendments]

Code of Federal Regulations Currentness
Title 21. Food and Drugs
Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)
Subchapter A. General
Part 10. Administrative Practices and Procedures (Refs & Annos)
Subpart B. General Administrative Procedures

➡§ 10.85 Advisory opinions.

(a) An interested person may request an advisory opinion from the Commissioner on a matter of general applicability.

(1) The request will be granted whenever feasible.

(2) The request may be denied if:

(i) The request contains incomplete information on which to base an informed advisory opinion;

(ii) The Commissioner concludes that an advisory opinion cannot reasonably be given on the matter involved;

(iii) The matter is adequately covered by a prior advisory opinion or a regulation;

(iv) The request covers a particular product or ingredient or label and does not raise a policy issue of broad applicability; or

(v) The Commissioner otherwise concludes that an advisory opinion would not be in the public interest.

(b) A request for an advisory opinion is to be submitted in accordance with § 10.20, is subject to the provisions of § 10.30 (c) through (l), and must be in the following form:

(Date) _____

_____

Division of Dockets Management, Food and Drug Administration, Department of Health and Human Services, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Request for Advisory Opinion

The undersigned submits this request for an advisory opinion of the Commissioner of Food and Drugs with respect to ____ (the general nature of the matter involved).

A. Issues involved.

(A concise statement of the issues and questions on which an opinion is requested.)

B. Statement of facts and law.

(A full statement of all facts and legal points relevant to the request.)

The undersigned certifies that, to the best of his/her knowledge and belief, this request includes all data, information, and views relevant to the matter, whether favorable or unfavorable to the position of the undersigned, which is the subject of the request.

(Signature) _____

_____

(Person making request)

_____

_____

(Mailing address)

_____

_____

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(Telephone number)

(c) The Commissioner may respond to an oral or written request to the agency as a request for an advisory opinion, in which case the request will be filed with the Division of Dockets Management and be subject to this section.

(d) A statement of policy or interpretation made in the following documents, unless subsequently repudiated by the agency or overruled by a court, will constitute an advisory opinion:

(1) Any portion of a Federal Register notice other than the text of a proposed or final regulation, e.g., a notice to manufacturers or a preamble to a proposed or final regulation.

(2) Trade Correspondence (T.C. Nos. 1-431 and 1A-8A) issued by FDA between 1938 and 1946.

(3) Compliance policy guides issued by FDA beginning in 1968 and codified in the Compliance Policy Guides manual.

(4) Other documents specifically identified as advisory opinions, e.g., advisory opinions on the performance standard for diagnostic X-ray systems, issued before July 1, 1975, and filed in a permanent public file for prior advisory opinions maintained by the Freedom of Information Staff (HFI-35).

(e) An advisory opinion represents the formal position of FDA on a matter and except as provided in paragraph (f) of this section, obligates the agency to follow it until it is amended or revoked. The Commissioner may not recommend legal action against a person or product with respect to an action taken in conformity with an advisory opinion which has not been amended or revoked.

(f) In unusual situations involving an immediate and significant danger to health, the Commissioner may take appropriate civil enforcement action contrary to an advisory opinion before amending or revoking the opinion. This action may be taken only with the approval of the Commissioner, who may not delegate this function. Appropriate amendment or revocation of the advisory opinion involved will be expedited.

(g) An advisory opinion may be amended or revoked at any time after it has been issued. Notice of amendment or revocation will be given in the same manner as notice of the advisory opinion was originally given or in the Federal Register, and will be placed on public display as part of the file on the matter in the office of the Division of Dockets Management. The Division of Dockets Management shall maintain a separate chronological index of all advisory opinions filed. The index will specify the date of the request for the advisory opinion, the date of the opinion, and identification of the appropriate file.

(h) Action undertaken or completed in conformity with an advisory opinion which has subsequently been amended or revoked is acceptable to FDA unless the Commissioner determines that substantial public interest considerations preclude continued acceptance. Whenever possible, an amended or revoked advisory opinion will state when action previously undertaken or completed does not remain acceptable, and any transition period that may be applicable.

(i) An interested person may submit written comments on an advisory opinion or modified advisory opinion. Four copies of any comments are to be sent to the Division of Dockets Management for inclusion in the public file on the advisory opinion. Individuals may submit only one copy. Comments will be considered in determining whether further modification of an advisory opinion is warranted.

(j) An advisory opinion may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as a legal requirement.

(k) A statement made or advice provided by an FDA employee constitutes an advisory opinion only if it is issued in writing under this section. A statement or advice given by an FDA employee orally, or given in writing but not under this section or § 10.90, is an informal communication that represents the best judgment of that employee at

that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

[44 FR 22323, April 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 59 FR 14364, March 28, 1994; 65 FR 56477, Sept. 19, 2000]

SOURCE: 44 FR 22323, April 13, 1979; 54 FR 6885, Feb. 15, 1989; 54 FR 39631, Sept. 27, 1989; 55 FR 9079, March 9, 1990; 58 FR 49190, Sept. 22, 1993; 62 FR 51512, Oct. 1, 1997; 63 FR 32735 , June 16, 1998; 65 FR 25440, May 2, 2000, unless otherwise noted.

AUTHORITY: 5 U.S.C. 551-558, 701-706; 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

21 C. F. R. § 10.85, **21 CFR § 10.85**

Current through July 19, 2007; 72 FR 39581

END OF DOCUMENT

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21 C.F.R. § 100.1

C

Effective: [See Text Amendments]

Code of Federal Regulations Currentness
Title 21. Food and Drugs
Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)
Subchapter B. Food for Human Consumption
Part 100. General (Refs & Annos)
Subpart A. State and Local Requirements (Refs & Annos)

→§ 100.1 Petitions requesting exemption from preemption for State or local requirements.

(a) Scope and purpose.

(1) This subpart applies to the submission and consideration of petitions under section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the act), by a State or a political subdivision of a State, requesting exemption of a State requirement from preemption under section 403A(a) of the act.

(2) Section 403A(b) of the act provides that where a State requirement has been preempted under section 403A(a) of the act, the State may petition the agency for an exemption. The agency may grant the exemption, under such conditions as it may prescribe by regulation, if the agency finds that the State requirement will not cause any food to be in violation of any applicable requirement under Federal law, will not unduly burden interstate commerce, and is designed to address a particular need for information that is not met by the preemptive Federal requirement.

(b) Definitions.

(1) Act means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

(2) Agency means the Food and Drug Administration.

(3) Commissioner means the Commissioner of Food and Drugs.

(4) State means a State as defined in section 201(a)(1) of the act (which includes a territory of the United States, the District of Columbia, and Puerto Rico) or any political subdivision of a State having authority to issue food standards and food labeling regulations having force of law.

(5) State requirement means any statute, standard, regulation, or other requirement that is issued by a State.

(c) Prerequisites for petitions for exemption from preemption. The Food and Drug Administration will consider a petition for exemption from preemption on its merits only if the petition demonstrates that:

(1) The State requirement was enacted or was issued as a final rule by an authorized official of the State and is in effect or would be in effect but for the provisions of section 403A of the act.

(2) The State requirement is subject to preemption under section 403A(a) of the act because of a statutory provision listed in that section or because of a Federal standard or other Federal regulation that is in effect, or that has been published as a final rule with a designated effective date, and that was issued under the authority of a statutory provision listed in that section. For the purposes of this subpart, all petitions seeking exemption from preemption under section 403A(a)(3) through (a)(5) of the act submitted before May 8, 1992, will be considered timely even though the applicable statutory provisions or regulations are not yet in effect.

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(3) The petitioner is an official of a State having authority to act for, or on behalf of, the Government in applying for an exemption of State requirements from preemption.

(4) The State requirement is subject to preemption under section 403A(a) of the act because it is not identical to the requirement of the preemptive Federal statutory provision or regulation including a standard of identity, quality, and fill. "Not identical to" does not refer to the specific words in the requirement but instead means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that:

(i) Are not imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act; or

(ii) Differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act.

(d) Form of petition.

(1) All information included in the petition should meet the general requirements of § 10.20(c) of this chapter.

(2) An original and one copy of the petition shall be submitted, or the petitioner may submit an original and a computer readable disk containing the petition. Contents of the disk should be in a standard format, such as ASCII format. (Petitioners interested in submitting a disk should contact the Center for Food Safety and Applied Nutrition for details.)

(3) Petitions for exemption from preemption for a State requirement shall be submitted to the Division of Dockets Management in the following form:

(Date) _____

Division of Dockets Management,

Food and Drug Administration,

Department of Health and Human Services,

rm. 1-23, 12420 Parklawn Dr.,

Rockville, MD 20857.

Petition Requesting Exemption from Preemption for State Requirement

The undersigned submits this petition under section 403A(b)of the Federal Food, Drug, and Cosmetic Act to request that the Food and Drug Administration exempt a State requirement from preemption.

The undersigned has authority to act for, or on behalf of, the (identify State or political subdivision of the State) because (document petitioner's authority to submit petition on behalf of the State).

A. Action Requested

1. Identify and give the exact wording of the State requirement and give date it was enacted or issued in final form.

2. Identify the specific standard or regulation that is believed to preempt the State requirement and the section and paragraph of the act that the standard or regulation implements.

B. Documentation of State Requirement

Provide a copy of the State requirement that is the subject of the application. Where available, the application should also include copies of any legislative history or background materials used in issuing the requirement, including hearing reports or studies concerning the development or consideration of the requirement.

C. Statement of Grounds

A petition for an exemption from preemption should contain the following:

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1. An explanation of the State requirement and its rationale, and a comparison of State and Federal requirements to show differences.

2. An explanation of why compliance with the State requirement would not cause a food to be in violation of any applicable requirement under Federal law.

3. Information on the effect that granting the State petition will have on interstate commerce. The petition should contain information on economic feasibility, i.e., whether the State and Federal requirements have significantly different effects on the production and distribution of the food product; comparison of the costs of compliance as shown by data or information on the actual or anticipated effect of the State and Federal requirements on the sale and price of the food product in interstate commerce; and the effect of the State requirement on the availability of the food product to consumers. To the extent possible, the petition should include information showing that it is practical and feasible for producers of food products to comply with the State requirement. Such information may be submitted in the form of statements from affected persons indicating their ability to comply.

4. Identification of a particular need for information that the State requirement is designed to meet, which need is not met by Federal law. The petition should describe the conditions that require the State to petition for an exemption, the information need that the State requirement fulfills, the inadequacy of the Federal requirement in addressing this need, and the geographical area or political subdivision in which such need exists.

D. Environmental Impact

The petition shall contain a claim for categorical exclusion under 21 CFR 25.24 or an environmental assessment under 21 CFR 25.31.

E. Notification

Provide name and address of person, branch, department, or other instrumentality of the State government that should be notified of the Commissioner's action concerning the petition.

F. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies.

(Signature) _____

(Name of petitioner) _____

(Mailing address) _____

(Telephone number) _____

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB number 0910-0277)

(e) Submission of petition for exemption; public disclosure. The availability for public disclosure of a petition for exemption will be governed by the rules specified in § 10.20(j) of this chapter.

(f) Agency consideration of petitions.

(1) Unless otherwise specified in this section, all relevant provisions and requirements of subpart B of part 10 of this chapter, are applicable to State petitions requesting exemption from Federal preemption under section 403A(b) of the act.

(2) If a petition does not meet the prerequisite requirements of paragraph (c) of this section, the agency will issue a letter to the petitioner denying the petition and stating in what respect the petition does not meet these requirements.

(3) If a petition appears to meet the prerequisite requirements in paragraph (c) of this section, it will be filed by the Division of Dockets Management, stamped with the date of filing, and assigned a docket number. The docket number identifies the file established by the

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Division of Dockets Management for all submissions relating to the petition, as provided in this part. Subsequent submissions relating to the matter must refer to the docket number and will be filed in the docket file. The Division of Dockets Management will promptly notify the petitioner in writing of the filing and docket number of a petition.

(4) Any interested person may submit written comments to the Division of Dockets Management on a filed petition as provided in § 10.30(d) of this chapter.

(5) Within 90 days of the date of filing the agency will furnish a response to the petitioner. The response will either:

(i) State that the agency has tentatively determined that the petition merits the granting of an exemption, and that it intends to publish in the Federal Register a proposal to grant the exemption through rulemaking;

(ii) Deny the petition and state the reasons for such denial; or

(iii) Provide a tentative response indicating why the agency has been unable to reach a decision on the petition, e.g., because of other agency priorities or a need for additional information.

(g) If a State submitted a petition for exemption of a State requirement from preemption under section 403A(a)(3) through (a)(5) of the act before May 8, 1992, that State requirement will not be subject to preemption until:

(1) November 8, 1992; or

(2) Action on the petition, whichever occurs later.

SOURCE: 42 FR 14306, March 15, 1977; 54 FR 39632, Sept. 27, 1989; 58 FR 2467, Jan. 6, 1993; 58 FR 2468, Jan. 6, 1993; 62 FR 51513, Oct. 1, 1997, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321, 331, 337, 342, 343, 348, 371.

21 C. F. R. § 100.1, **21 CFR § 100.1**

Current through July 19, 2007; 72 FR 39581

END OF DOCUMENT

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C

Effective: April 01, 2006

Code of Federal Regulations Currentness
Title 21. Food and Drugs
Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)
Subchapter B. Food for Human Consumption
Part 101. Food Labeling (Refs & Annos)
Subpart A. General Provisions

➡§ 101.4 Food; designation of ingredients.

(a)(1) Ingredients required to be declared on the label or labeling of a food, including foods that comply with standards of identity, except those ingredients exempted by § 101.100, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of § 101.2, except that ingredients in dietary supplements that are listed in the nutrition label in accordance with § 101.36 need not be repeated in the ingredient list. Paragraph (g) of this section describes the ingredient list on dietary supplement products.

(2) The descending order of predominance requirements of paragraph (a)(1) of this section do not apply to ingredients present in amounts of 2 percent or less by weight when a listing of these ingredients is placed at the end of the ingredient statement following an appropriate quantifying statement, e.g., "Contains ___ percent or less of ____," or "Less than ___ percent of ____." The blank percentage within the quantifying statement shall be filled in with a threshold level of 2 percent, or, if desired, 1.5 percent, 1.0 percent, or 0.5 percent, as appropriate. No ingredient to which the quantifying phrase applies may be present in an amount greater than the stated threshold.

(b) The name of an ingredient shall be a specific name and not a collective (generic) name, except that:

(1) Spices, flavorings, colorings and chemical preservatives shall be declared according to the provisions of § 101.22.

(2) An ingredient which itself contains two or more ingredients and which has an established common or usual name, conforms to a standard established pursuant to the Meat Inspection or Poultry Products Inspection Acts by the U.S. Department of Agriculture, or conforms to a definition and standard of identity established pursuant to section 401 of the Federal Food, Drug, and Cosmetic Act, shall be designated in the statement of ingredients on the label of such food by either of the following alternatives:

(i) By declaring the established common or usual name of the ingredient followed by a parenthetical listing of all ingredients contained therein in descending order of predominance except that, if the ingredient is a food subject to a definition and standard of identity established in subchapter B of this chapter that has specific labeling provisions for optional ingredients, optional ingredients may be declared within the parenthetical listing in accordance with those provisions.

(ii) By incorporating into the statement of ingredients in descending order of predominance in the finished food, the common or usual name of every component of the ingredient without listing the ingredient itself.

(3) Skim milk, concentrated skim milk, reconstituted skim milk, and nonfat dry milk may be declared as "skim milk" or "nonfat milk".

(4) Milk, concentrated milk, reconstituted milk, and dry whole milk may be declared as "milk".

(5) Bacterial cultures may be declared by the

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word "cultured" followed by the name of the substrate, e.g., "made from cultured skim milk or cultured buttermilk".

(6) Sweetcream buttermilk, concentrated sweetcream buttermilk, reconstituted sweetcream buttermilk, and dried sweetcream buttermilk may be declared as "buttermilk".

(7) Whey, concentrated whey, reconstituted whey, and dried whey may be declared as "whey".

(8) Cream, reconstituted cream, dried cream, and plastic cream (sometimes known as concentrated milk fat) may be declared as "cream".

(9) Butteroil and anhydrous butterfat may be declared as "butterfat".

(10) Dried whole eggs, frozen whole eggs, and liquid whole eggs may be declared as "eggs".

(11) Dried egg whites, frozen egg whites, and liquid egg whites may be declared as "egg whites".

(12) Dried egg yolks, frozen egg yolks, and liquid egg yolks may be declared as "egg yolks".

(13) [Reserved]

(14) Each individual fat and/or oil ingredient of a food intended for human consumption shall be declared by its specific common or usual name (e.g., "beef fat", "cottonseed oil") in its order of predominance in the food except that blends of fats and/or oils may be designated in their order of predominance in the foods as "_____ shortening" or "blend of _____ oils", the blank to be filled in with the word "vegetable", "animal", "marine", with or without the terms "fat" or "oils", or combination of these, whichever is applicable if, immediately following the term, the common or usual name of each individual vegetable, animal, or marine fat or oil is given in parentheses, e.g., "vegetable oil shortening (soybean and cottonseed oil)". For products that are blends of fats and/or oils and for foods in which fats and/or oils constitute the predominant ingredient, i.e., in which the combined weight of all fat and/or oil ingredients equals or exceeds the weight of the most predominant ingredient that is not a fat or oil, the listing of the common or usual names of such fats and/or oils in parentheses shall be in descending order of predominance. In all other foods in which a blend of fats and/or oils is used as an ingredient, the listing of the common or usual names in parentheses need not be in descending order of predominance if the manufacturer, because of the use of varying mixtures, is unable to adhere to a constant pattern of fats and/or oils in the product. If the fat or oil is completely hydrogenated, the name shall include the term hydrogenated, or if partially hydrogenated, the name shall include the term partially hydrogenated. If each fat and/or oil in a blend or the blend is completely hydrogenated, the term "hydrogenated" may precede the term(s) describing the blend, e.g., "hydrogenated vegetable oil (soybean, cottonseed, and palm oils)", rather than preceding the name of each individual fat and/or oil; if the blend of fats and/or oils is partially hydrogenated, the term "partially hydrogenated" may be used in the same manner. Fat and/or oil ingredients not present in the product may be listed if they may sometimes be used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as "or", "and/or", "contains one or more of the following:", e.g., "vegetable oil shortening (contains one or more of the following: cottonseed oil, palm oil, soybean oil)". No fat or oil ingredient shall be listed unless actually present if the fats and/or oils constitute the predominant ingredient of the product, as defined in this paragraph (b)(14).

(15) When all the ingredients of a wheat flour are declared in an ingredient statement, the principal ingredient of the flour shall be declared by the name(s) specified in §§ 137.105 , 137.200, 137.220 and 137.225 of this chapter, i.e., the first ingredient designated in the ingredient list of flour, or bromated flour, or enriched flour, or self-rising flour is "flour",

"white flour", "wheat flour", or "plain flour"; the first ingredient designated in the ingredient list of durum flour is "durum flour"; the first ingredient designated in the ingredient list of whole wheat flour, or bromated whole wheat flour is "whole wheat flour", "graham flour", or "entire wheat flour"; and the first ingredient designated in the ingredient list of whole durum wheat flour is "whole durum wheat flour".

(16) Ingredients that act as leavening agents in food may be declared in the ingredient statement by stating the specific common or usual name of each individual leavening agent in parentheses following the collective name "leavening", e.g., "leavening (baking soda, monocalcium phosphate, and calcium carbonate)". The listing of the common or usual name of each individual leavening agent in parentheses shall be in descending order of predominance: Except, That if the manufacturer is unable to adhere to a constant pattern of leavening agents in the product, the listing of individual leavening agents need not be in descending order of predominance. Leavening agents not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as "or", "and/or", "contains one or more of the following:".

(17) Ingredients that act as yeast nutrients in foods may be declared in the ingredient statement by stating the specific common or usual name of each individual yeast nutrient in parentheses following the collective name "yeast nutrients", e.g., "yeast nutrients (calcium sulfate and ammonium phosphate)". The listing of the common or usual name of each individual yeast nutrient in parentheses shall be in descending order of predominance: Except, That if the manufacturer is unable to adhere to a constant pattern of yeast nutrients in the product, the listing of the common or usual names of individual yeast nutrients need not be in descending order of predominance. Yeast nutrients not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as "or", "and/or", or "contains one or more of the following:".

(18) Ingredients that act as dough conditioners may be declared in the ingredient statement by stating the specific common or usual name of each individual dough conditioner in parentheses following the collective name "dough conditioner", e.g., "dough conditioners (L-cysteine, ammonium sulfate)". The listing of the common or usual name of each dough conditioner in parentheses shall be in descending order of predominance: Except, That if the manufacturer is unable to adhere to a constant pattern of dough conditioners in the product, the listing of the common or usual names of individual dough conditioners need not be in descending order of predominance. Dough conditioners not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as "or", "and/or", or "contains one or more of the following:".

(19) Ingredients that act as firming agents in food (e.g., salts of calcium and other safe and suitable salts in canned vegetables) may be declared in the ingredient statement, in order of predominance appropriate for the total of all firming agents in the food, by stating the specific common or usual name of each individual firming agent in descending order of predominance in parentheses following the collective name "firming agents". If the manufacturer is unable to adhere to a constant pattern of firming agents in the food, the listing of the individual firming agents need not be in descending order of predominance. Firming agents not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as "or", "and/or", "contains one or more of the following:".

(20) For purposes of ingredient labeling, the term sugar shall refer to sucrose, which is obtained from sugar cane or sugar beets in accordance with the provisions of § 184.1854 of this chapter.

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(21) [Reserved]

(22) Wax and resin ingredients on fresh produce when such produce is held for retail sale, or when held for other than retail sale by packers or repackers shall be declared collectively by the phrase "coated with food-grade animal-based wax, to maintain freshness" or the phrase "coated with food-grade vegetable-, petroleum-, beeswax-, and/or shellac-based wax or resin, to maintain freshness" as appropriate. The terms "food-grade" and "to maintain freshness" are optional. The term lac-resin may be substituted for the term shellac.

(23) When processed seafood products contain fish protein ingredients consisting primarily of the myofibrillar protein fraction from one or more fish species and the manufacturer is unable to adhere to a constant pattern of fish species in the fish protein ingredient, because of seasonal or other limitations of species availability, the common or usual name of each individual fish species need not be listed in descending order of predominance. Fish species not present in the fish protein ingredient may be listed if they are sometimes used in the product. Such ingredients must be identified by words indicating that they may not be present, such as "or", "and/or", or "contains one or more of the following:" Fish protein ingredients may be declared in the ingredient statement by stating the specific common or usual name of each fish species that may be present in parentheses following the collective name "fish protein", e.g., "fish protein (contains one or more of the following: Pollock, cod, and/or pacific whiting)".

(c) When water is added to reconstitute, completely or partially, an ingredient permitted by paragraph (b) of this section to be declared by a class name, the position of the ingredient class name in the ingredient statement shall be determined by the weight of the unreconstituted ingredient plus the weight of the quantity of water added to reconstitute that ingredient, up to the amount of water needed to reconstitute the ingredient to single strength. Any water added in excess of the amount of water needed to reconstitute the ingredient to single strength shall be declared as "water" in the ingredient statement.

(d) When foods characterized on the label as "nondairy" contain a caseinate ingredient, the caseinate ingredient shall be followed by a parenthetical statement identifying its source. For example, if the manufacturer uses the term "nondairy" on a creamer that contains sodium caseinate, it shall include a parenthetical term such as "a milk derivative" after the listing of sodium caseinate in the ingredient list.

(e) If the percentage of an ingredient is included in the statement of ingredients, it shall be shown in parentheses following the name of the ingredient and expressed in terms of percent by weight. Percentage declarations shall be expressed to the nearest 1 percent, except that where ingredients are present at levels of 2 percent or less, they may be grouped together and expressed in accordance with the quantifying guidance set forth in paragraph (a)(2) of this section.

(f) Except as provided in § 101.100, ingredients that must be declared on labeling because there is no label for the food, including foods that comply with standards of identity, shall be listed prominently and conspicuously by common or usual name in the manner prescribed by paragraph (b) of this section.

(g) When present, the ingredient list on dietary supplement products shall be located immediately below the nutrition label, or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label and shall be preceded by the word "Ingredients," unless some ingredients (i.e., sources) are identified within the nutrition label in accordance with § 101.36(d), in which case the ingredients listed outside the nutrition label shall be in a list preceded by the words "Other ingredients." Ingredients in dietary supplements that are not dietary ingredients or that do not contain dietary ingredients, such as excipients, fillers, artificial colors, artificial sweeteners, flavors, or binders, shall be included in the ingredient list.

(h) The common or usual name of ingredients of dietary supplements that are botanicals (including fungi and algae) shall be consistent with the names

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standardized in Herbs of Commerce, 1992 edition, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Herbal Products Association, 8484 Georgia Ave., suite 370, Silver Spring, MD 20910, 301-588-1171, FAX 301-588-1174, e-mail: ahpa@ahpa.org, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations /ibr_locations.html. The listing of these names on the label shall be followed by statements of:

(1) The part of the plant (e.g., root, leaves) from which the dietary ingredient is derived (e.g., "Garlic bulb" or "Garlic (bulb)"), except that this designation is not required for algae. The name of the part of the plant shall be expressed in English (e.g., "flower" rather than "flos");

(2) The Latin binomial name of the plant, in parentheses, except that this name is not required when it is available in the reference entitled: Herbs of Commerce for the common or usual name listed on the label, and, when required, the Latin binomial name may be listed before the part of the plant. Any name in Latin form shall be in accordance with internationally accepted rules on nomenclature, such as those found in the International Code of Botanical Nomenclature and shall include the designation of the author or authors who published the Latin name, when a positive identification cannot be made in its absence. The International Code of Botanical Nomenclature (Tokyo Code), 1994 edition, a publication of the International Association for Plant Taxonomy, is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the International Code of Botanical Nomenclature may be obtained from Koeltz Scientific Books, D-61453 Konigstein, Germany, and University Bookstore, Southern Illinois University, Carbondale, IL 62901-4422, 618-536-3321, FAX 618-453-5207, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_ regulations/ibr_locations.html.

(3) On labels of single-ingredient dietary supplements that do not include an ingredient list, the identification of the Latin binomial name, when needed, and the part of the plant may be prominently placed on the principal display panel or information panel, or included in the nutrition label.

[42 FR 14308, March 15, 1977; 43 FR 12858, March 28, 1978; 43 FR 24519, June 6, 1978; 48 FR 8054, Feb. 25, 1983; 55 FR 17433, April 25, 1990; 58 FR 2875, Jan. 6, 1993; 62 FR 49847, Sept. 23, 1997; 62 FR 64634, Dec. 8, 1997; 64 FR 50448, Sept. 17, 1999; 66 FR 17358, March 30, 2001; 68 FR 51704, Aug. 28, 2003; 70 FR 76685, Dec. 28, 2005; 72 FR 11776, March 14, 2007]

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